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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/063,477	04/20/1998	ROBERT A. HOLTON	FSU-10302	4505
321	7590	09/26/2005	EXAMINER	
SENNIGER POWERS LEAVITT AND ROEDEL ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			DESAI, RITA J	
		ART UNIT	PAPER NUMBER	
		1625		

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/063,477	HOLTON ET AL. 3
	<b>Examiner</b>	<b>Art Unit</b>
	Rita J. Desai	1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 01 March 2005.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-19 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 1-19 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date 9/14/05.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_

## **DETAILED ACTION**

Claims 1-19 are pending.

The examiner tried to understand the explanation offered by Mr. Brad Schammel on 9/14/05 but was not convinced. Examiner suggested inserting “in the absence of a base” into claim 1 to over come the prior art.

### **New Ground of Rejection**

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

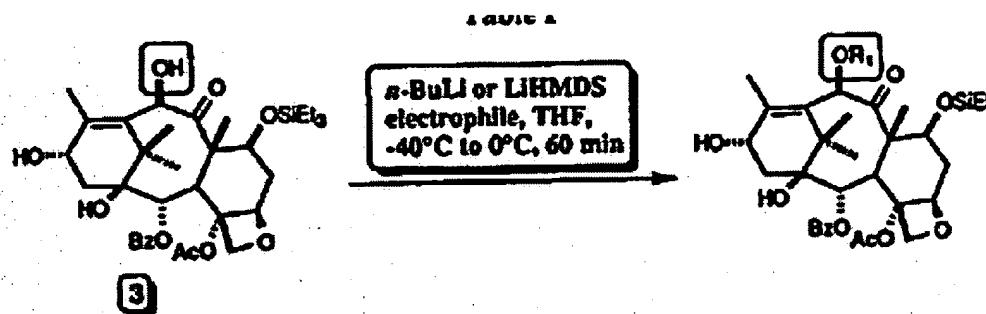
Claims 1, 3, 4, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Kant et al 1994, A Chemoselective Approach to Functionalize...

The reference discloses a process of acylating the C10 position Taxane without using a base.

The electrophile acts as an acylating agent.

Applicants claim recites using less than 1 equivalent of amine base and the specifications teaches in the absence of a base.

See table I



R1 is a acyl group.

Applicants claim 1 just recites acylating a C10 hydroxy using an acylating agent in less than 1 equivalent of base.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chemical Studies of 10-deacetyl baccatin III Tetrahedron 1986, F. Gueritte –Voeglein et al.

And Kant et al 1994, A Chemoselective Approach to Functionalize...

Applicants claims are drawn to a process of acylation of C10 hydroxy group of taxane with a reaction mixture having less than 1:1 equivalent of amine base to the taxane. The taxane reacted is 10-deacetyl baccatin III.

Applicants specifications indicates using a base in different ratios including 100:1 , 10:1 of amine to toxane or even in the absence of an amine base.

**Determination of the scope and content of the prior art (MPEP §2141.01)**

The reference Chemical Studies of 10-deacetyl baccatin III Tetrahedron 1986, F. Gueritte –Voegelein et al.

uses the same taxane and acylated the C10 hydroxy group as given on page 4455.

It uses Pyridine as an amine and acylates the C10 hydroxy.

See the whole reference , See compound 27 on page 4455.

Kant et al 1994, A Chemoselective Approach to Functionalize... teaches the acylation of the C10 , in the absence of a base.

**Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)**

The reference does not clearly teach the amount of pyridine used. In its chemical reaction it indicates it is 1 molecule of pyridine to 1 molecule of 10-deacetyl baccatin III.

The amount of base used is just the optimization of the conditions.

Kant reference teaches that acylation of the same C10 position can be carried out in the absence of base.

**Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)**

Thus it is *prima facie* obvious to optimize the conditions to obtain the preferred acylated position. Kant discloses the acylation in the absence of a base and Gueritte –Voegelein et al. teaches using pyridine without specifying how much.

Since Kant teaches absence of a base and Gueritte –Voegelein et al.

Does not teach how much, it is obvious that the base is not a critical reagent for the invention. Hence adding a limitation less than 1 equivalent is immaterial to the patentability of the invention and is *prima facie* obvious to change amount.

### ***Conclusion***

The claims 1-19 are not found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai  
Primary Examiner  
Art Unit 1625

R.D.  
September 14, 2005



Rita J. Desai  
9/16/05